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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,829	11/10/2000	James J. Fort	6488.US.02	3590

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/709,829	FORT ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11,19-21 and 30-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-11,19-21,30-32 and 34-37* is/are rejected.

7)☒ Claim(s) *6,33 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060901*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 1, 2006 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 5, 7-11, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the claim limitation requiring the HIV protease inhibitors in general, or the specific HIV inhibitors other than ABT-538, to be in amorphous form. The only original disclosure of amorphous protease inhibitors that the examiner has been able to locate is in the headings and the brief descriptions of Figures 1 and 2, and this disclosure is limited to the specific protease inhibitor ABT-538 (i.e. ritonavir). There is no discussion of the significance of this form of ABT-538, there is no disclosure that other protease inhibitors should have the same form as ABT-538, and thus there is no basis for inferring that other HIV protease inhibitors should or can be in an amorphous form. The original disclosure contains no indication that Applicants contemplated that HIV protease inhibitors in general, or that specific HIV protease inhibitors other than ABT-538, should be in an amorphous form.

4. Claims 5, 6, and 20 are objected to because of the following informalities: In claims 5, 6, and 20, there is one more beginning parenthesis than end parenthesis in the chemical name for ritonavir. It appears that an end parenthesis should be inserted between "amino" and "-2-". Appropriate correction is required.

5. Applicants may wish to amend claim 7 is the same manner that this compound name was amended in claims 1 and 8.

6. Applicant is advised that should claim 37 be found allowable, claim 31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof; and should claim 33 be found allowable, claims 6 and 38 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 31 and 37 are identical in scope. Claims 6, 33, and 38 are identical in scope.

7. Claims 30, 31, 35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Al-Razzak et al (U.S. Patent No. 5,610,193). Al-Razzak et al teach a solid dispersion comprising compound III, i.e. ritonavir, in polyethylene glycol 1450 encapsulated in a hard gelatin capsule. The compositions are administered to inhibit HIV infection and to treat AIDS in humans. See, e.g., column 9, Example 4 and lines 42-64. Because the compositions of Al-Razzak et al are prepared by solvent evaporation as are Applicants' solid dispersions, because the same water soluble carriers are used by Al-Razzak et al as are claimed by Applicants, and because no special steps are taken by Al-Razzak et al to produce its HIV protease inhibitors in crystalline form, the

HIV protease inhibitors in the compositions of Al-Razzak et al are deemed inherently to be in amorphous form to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the compositions of Al-Razzak et al and Applicants' claimed solid dispersions to shift the burden to Applicants to provide evidence that the claimed solid dispersions are unobviously different than those of Al-Razzak et al.

8. Claims 32 and 34 are rejected under 35 U.S.C. 103(a) as being obvious over Al-Razzak et al (U.S. Patent No. 5,610,193) as applied against claims 30, 31, 35, and 37 above, and further in view of Sham et al (U.S. Patent No. 5,914,332). Al-Razzak et al disclose including an HIV protease inhibitor generically, but do not teach a combination of ritonavir and ABT-378. Sham et al teach the desirability of administering combinations of ritonavir and ABT-378. See, e.g., column 79, lines 50-63, and column 82, lines 1-19 and 35-41. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include ABT-378 in the composition of Example 4 of Al-Razzak et al because the compositions of Al-Razzak et al are applicable to HIV protease inhibitors generically and would permit the oral administration of Sham et al's active agents, because Sham et al disclose the desirability of administering combinations of ritonavir and ABT-378, and because in the HIV treatment art it is desirable to administer multiple active agents so as to prevent the development of resistant virus strains. Note that the new claims do not require the ABT-378 to be in amorphous form.

9. Claim 36 is rejected under 35 U.S.C. 103(a) as being obvious over Al-Razzak et al (U.S. Patent No. 5,610,193) as applied against claims 30, 31, 35, and 37 above, and further in view of Franson et al (U.S. Patent No. 6,197,787). Al-Razzak et al teach their solid dispersion in the form of a capsule, but not in the form of a tablet. Franson et al teach that solid dispersions

comprising poorly soluble drug substances can be made into the form of capsules or tablets. See, e.g., the Abstract. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to make the solid dispersion of Example 4 of Al-Razzak et al in the form of a tablet because Franson et al teach that these are known physical forms for administration of a solid dispersion comprising a poorly soluble drug substance, and the change in physical form would not have been expected to affect materially the administration characteristics of the solid dispersion of Example 4 of Al-Razzak et al.

10. Applicant's arguments filed September 1, 2006 have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 112, first paragraph, is maintained. While ABT-378 and nelfinavir are prepared similarly to ritonavir in Applicants' specification, Applicants did not submit any evidence that so-prepared ABT-378 and nelfinavir were actually produced in amorphous form. Further, even if a few HIV protease inhibitors were produced in amorphous form in the specification, this does not support claim language drawn to the entire genus of HIV protease inhibitors in amorphous form, especially where there is no discussion of the significance of this form for ritonavir and there is no disclosure that all other protease inhibitors should have the same form as ritonavir.

The rejections based upon the Aungst et al article (Int. J. Pharmaceutics, Vol. 156, pages 79-88) and the Aungst et al article (B.T. Gattetosse, Vol. 87, pages 49-54) are withdrawn. Because the two articles describes the PEG solid dispersions as being "unsuccessful", at least for the tested drug concentrations, there would be no motivation to alter and/or optimize the PEG molecular weight of the vehicles so as to arrive at Applicants' claimed composition.

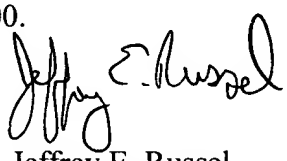
Al-Razzak et al (U.S. Patent No. 5,610,193) is not applied against those claims specifying a PEG molecular weight of 8000. The highest PEG molecular weight disclosed by Al-Razzak et al is 1450 (see Example 4). The difference between this molecular weight and the claimed PEG molecular weight of 8000 is so great as to be nonobvious.

The anticipation rejection based upon Al-Razzak et al (U.S. Patent No. 5,610,193) is maintained against new claims 30, 31, 35, and 37. Exhibit 1 attached to Applicants' response (although not prior art to the claimed invention) supports the examiner's position that the ritonavir present in Al-Razzak et al's composition is inherently in amorphous form. As indicated at page 22, column 2, under "Amorphous materials", amorphous drug forms are frequently produced in the absence of special crystallization techniques. The amorphous form is the presumptive form for complex organic compounds. Applicants have provided no evidence indicating that the ritonavir present in Al-Razzak et al's composition is in crystalline form.

11. Claims 33 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

October 3, 2006